

# SUPPLEMENTAL PERMIT CONDITIONS For Release of aspen USDA-APHIS- BRS Permit 06-172-01r

# I. Compliance with Regulations

- 1. Any regulated article introduced not in compliance with the requirements of 7 Code of Federal Regulation Part 340 or any standard or supplemental permit conditions, shall be subject to the immediate application of such remedial measures or safeguards as an inspector determines necessary, to prevent the introduction of such plant pests. The responsible party may be subject to fines or penalties as authorized by the Plant Protection Act (7 U.S.C. 7701-7772).
- 2. This Permit (APHIS form 2000) does not eliminate the permittee's legal responsibility to obtain all necessary Federal and State approvals, including: (A) for the use of any non-genetically engineered plant pest or pathogens as challenge inoculum; (B) plants, plant parts or seeds which are under existing Federal or State quarantine or restricted use; (C) experimental use of unregistered chemicals; and (D) food, feed, pharmacological, biologic, or industrial use of regulated articles or their products and co-mingled plant material. In the latter case, depending on the use, reviews by APHIS, the U.S. Food and Drug Administration, or the U.S. Environmental Protection Agency may be necessary.
- 3. The procedures, processes, and safeguards used to prevent escape, dissemination, and persistence of the regulated article as described in the permit application and in the supplemental permit conditions must be strictly followed. The permittee must maintain records sufficient to verify compliance with these procedures. APHIS, BRS must be notified of any proposed changes to protocols referenced in the permit application.

# II. Reporting Unauthorized Releases and Unintended Effects

- 1. According to the regulation in 7 CFR § 340.4(f)(10)(i), APHIS shall be notified orally immediately upon discovery and notified in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article.
  - For immediate oral notification, contact APHIS/BRS Compliance Staff at (301) 734-5690 and ask to speak to a Compliance and Inspection staff member.
  - In the event of an emergency and you are unable to reach the BRS Compliance Staff at the above number, you may call:

The APHIS/BRS Regional Biotechnology Coordinator assigned to the state, where the field test occurs

For Western Region, contact Ralph Stoaks by phone at (970) 494-7573 or e-mail ralph.d.stoaks@aphis.usda.gov

Or

The APHIS/PPQ Regional Biotechnology Coordinator assigned to the state where the field test occurs

<u>For Western Region</u>, contact Stacy Scott by phone at 970-494-7577 or e-mail <u>Stacy.E.Scott@aphis.usda.gov</u>

Or

The APHIS State Plant Health Director for the state where the field test occurs. The list of APHIS State Plant Health Director is available at <a href="http://ceris.purdue.edu/napis/names/sphdXstate.html">http://ceris.purdue.edu/napis/names/sphdXstate.html</a>
Barbara Chambers/ Seattle 206-592-9057

- 2. According to the regulation in 7 CFR § 340.4(f)(10)(ii), APHIS shall be notified in writing as soon as possible but within 5 working days if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the permit application or suffers any unusual occurrence (excessive mortality or morbidity, or unanticipated effect on non-target organisms).
- 3. Written notification should be sent by one of the following means:

## By e-mail:

BRSCompliance@aphis.usda.gov

#### By mail:

Biotechnology Regulatory Services (BRS) Compliance and Inspection Branch USDA/APHIS 4700 River Rd. Unit 147 Riverdale, MD 20737

## III. Perimeter Fallow Zone

The perimeter surrounding the test beds used in this trial may be unplanted or planted in grass and managed to control excessive weed growth.

A 50 ft fallow zone is NOT required.

# IV. Dedicated Planting and Harvesting

Given the nature of this trial, this is not required.

# V. Cleaning of Equipment

Given the nature of this trial, specific SOPs describing equipment cleaning are not required.

# VI. Use of Dedicated Storage Facilities

Not applicable.

# VII. Post Trial Monitoring

The applicant has described devitalization of all plant material and removal of all soil from the test beds in his permit application. Viable plant material should not remain at the test site following termination. When this has been demonstrated to BRS and assessed by an APHIS inspector, no post trial monitoring will be required.

## VIII. Post Harvest Land Use Restrictions

 When condition VII. above has been satisfied, no post harvest land use restrictions will be required.

# IX. Inspections

- APHIS Biotechnology Regulatory Services (BRS) and/or an APHIS/PPQ Regional Biotechnologist, APHIS/BRS Regional Biotechnology Coordinator or APHIS State Plant Health Director may conduct inspections of the test site, facilities, and/or records at any time.
- 2. APHIS may invite State Regulatory Officials to participate in these inspections.
- 3. Inspections will include examination of records that verify compliance with regulations.

# X. Reports and Notices

Send notices and all reports (CBI and CBI deleted or non CBI copies) to BRS by e-mail, mail, or fax.

## **BRS E-mail:**

BRSCompliance@aphis.usda.gov

#### **BRS Mail:**

Biotechnology Regulatory Services (BRS) Compliance and Inspection Branch USDA/APHIS 4700 River Rd. Unit 147 Riverdale, MD 20737

### **BRS Fax:**

Compliance and Inspection Branch (301) 734-8669

In addition, fax or email the CBI deleted or non CBI version of the pre-planting and pre-harvest (termination) notices to the State Regulatory Official(s)

Dr. Brad White, Program Manager bwhite@agr.wa.gov 360-902-2071---- voice 360-902-2094---fax

## 1. Planting Report

Within 28 calendar days after planting, submit a planting report that includes the following information for each field test site:

- i. The location and the approximate number and/or acres of transgenic plants which were actually planted
- ii. The total acreage of the test plot
- iii. The actual planting date.

## 2. Annual report

The applicant must submit a report within 30 days of the 1 year anniversary of the permit approval date that describes on-going activities and summarized results from the approved trial plantings.

## 3. Pre-Harvest/Termination Notice

At least 21 calendar days prior to the anticipated harvest or termination, submit a Notice indicating the planned date of harvest or termination and the contact information for each field test site.

#### 4. Field Test Report

Within 6 months after the end of the field test (final harvest or crop destruct), the permittee is required to submit a field test report. Field test reports shall include:

- i. APHIS reference number
- ii. A summary of data from the trial
- iii. Analysis of any deleterious effects on plants, non-target organisms, or the environment.
- iv. A description of how, when and where the plant materials were disposed of.